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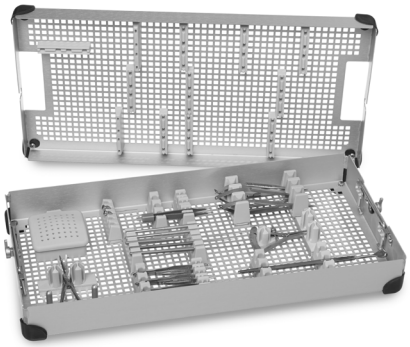

(EN) INSTRUMENT PROTECTION SYSTEMS **INSTRUCTIONS FOR USE: English**

(FR) SYSTÈMES DE PROTECTION DES INSTRUMENTS **MODE D'EMPLOI: Français**

(DE) INSTRUMENTENSCHUTZSYSTEME **GEBRAUCHSANWEISUNG: Deutsch**

(IT) SISTEMI DI PROTEZIONE PER STRUMENTI **ISTRUZIONI PER L'USO: Italiano**

(ES) SISTEMAS DE PROTECCIÓN DE INSTRUMENTAL **INSTRUCCIONES DE USO: Español**

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(SV) SKYDDSSYSTEM FÖR INSTRUMENT **ANVÄNDARINSTRUKTIONER: Svenska**

(DA) INSTRUMENTBESKYTTELSESSYSTEMER **BRUGSANVISNING: Dansk**

(FI) INSTRUMENTTIEN SUOJAUSJÄRJESTELMÄ **KÄYTTÖOHJEET: Suomi**

(EL) ΣΥΣΤΗΜΑΤΑ ΠΡΟΣΤΑΣΙΑΣ ΟΡΓΑΝΩΝ **ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ: Ελληνικά**

(PL) SYSTEM OCHRONY NARZĘDZI **INSTRUKCJA UŻYTKOWANIA: Polski**

(TR) ALET KORUMA SİSTEMLERİ **KULLANMA TALİMATLARI: Türkçe**

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(SK) SYSTÉMY OCHRANY NÁSTROJOV **POKYNY NA POUŽITIE: Slovenčina**

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(ET) INSTRUMENDI KAITSESÜSTEEMID **KASUTUSJUHEND: Eesti**

(LV) INSTRUMENTU AIZSARDZĪBAS SISTĒMAS **LIETOŠANAS INSTRUKCIJA: Latviski**

(HR) SUSTAVI ZAŠTITE INSTRUMENATA **UPUTE ZA UPORABU: Hrvatski**

(SR) SISTEMI ZA ZAŠTITU INSTRUMENATA **UPUTSTVA ZA UPOTREBU: Srpski**

(LT) INSTRUMENTŲ APSAUGOS SISTEMOS **NAUDOJIMO INSTRUKCIJA: Lietuvių k.**

(ZH-CN) 器械保护系统 **使用说明书: 简体中文**

(ZH) 器械保護系統 **使用說明書: 繁體中文**

(KO) 기기 보호 시스템 **용도 표기: 한국어**

(JA) 医療器具プロテクションシステム **取扱説明書: 日本語**

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If you have any questions, please contact our customer service representatives at **1.888.229.2875**. / Pour toute question, veuillez contacter nos représentants du service clientèle au **1.888.229.2875**. / Wenn Sie Fragen haben, wenden Sie sich an unsern Kundendienst unter **1.888.229.2875**. / In caso di domande, contattare gli addetti all'assistenza clienti al numero **1.888.229.2875**. / Si tiene alguna pregunta, póngase en contacto con nuestros representantes de servicio de atención al cliente al **1.888.229.2875**. / Se você tiver alguma dúvida, entre em contato com nossos representantes de atendimento ao cliente pelo telefone **1.888.229.2875**. / Neem voor vragen contact op met onze medewerkers van de klantenservice op **1.888.229.2875**. / Om du har frågor, var god kontakta våra kundtjänstrepresentanter på telefon **1.888.229.2875**. / Hvis du har spørgsmål, bedes du kontakte vores kundeservicerepræsentanter på **1.888.229.2875**. / Jos sinulla on kysyttävää, ota yhteyttä asiakaspalveluumme puhelinnumerossa **1.888.229.2875**. / Αν έχετε ερωτήσεις, επικοινωνήστε με τους αντιπροσώπους της εξυπηρέτησης πελατών μας στο **1.888.229.2875**. / Wszelkie pytania należy kierować do przedstawicieli działu obsługi klienta pod numerem telefonu **1.888.229.2875**. / Herhangi bir sorunuz varsa, lütfen şu numaradan müşteri hizmetleri temsilcilerimizi arayın: **1.888.229.2875**. / Если у вас есть какие-либо вопросы, свяжитесь с представителями нашей службы поддержки клиентов по телефону **1.888.229.2875**. / Máte-li nějaké dotazy, obraťte se na naše zástupce služeb pro zákazníky na čísle **1.888.229.2875**. / Ha bármilyen kérdése van, kérjük, vegye fel a kapcsolatot ügyfélszolgálati képviselőinkkel az telefonszámon **1.888.229.2875**. / Ak máte akékoľvek otázky, obráťte sa na našich zástupcov zákazníckeho servisu na čísle **1.888.229.2875**. / Hvis du har noen spørsmål, ta kontakt med våre kundeservicerepresentanter på **1.888.229.2875**. / Če imate kakršna koli vprašanja, se obrnite na naše predstavnike službe za stranke na **1.888.229.2875**. / Ако имате някакви въпроси, моля, свържете се с нашите представители за обслужване на клиенти на **1.888.229.2875**. / Dacă aveți întrebări, vă rugăm să contactați reprezentanții departamentului nostru de relații clienți la **1.888.229.2875**. / Küsimuste korral võtke ühendust meie klienditeenindusega **1.888.229.2875**. / Ja rodas jautājumi, lūdzu, sazinieties ar mūsu klientu apkalpošanas nodaļas pārstāvjiem pa tālruni **1.888.229.2875**. / Ako imate bilo kakva pitanja, nazovite predstavnika naše korisničke službe na **1.888.229.2875**. / Ako imate pitanja, obratite se predstavnicima korisničke podrške na **1.888.229.2875**. / Jei turite klausimų, susisiekite su mūsų klientų aptarnavimo atstovais telefonu **1.888.229.2875**. / 如有任何疑问，请致电 **1.888.229.2875** 与我们的客户服务代表联系。 / 如有任何疑問，請撥打電話 **1.888.229.2875** 與我們的客戶服務代表聯絡。 / 질문이 있는 경우, **1.888.229.2875**의 고객 서비스 대표번호로 문의하십시오. / ご不明な点がございましたら、以下のカスタマーサービス担当者までお問い合わせください **1.888.229.2875**

The instructions provided within have been validated by the device manufacturer as being capable of reprocessing reusable medical devices.

Individual sterilizers, instrument cleanliness, specific loading of instrument trays, types and geometry of instruments, sterilization containers, filters, and wrappings vary at each location.

READ THIS SECTION BEFORE PLACING PRODUCT INTO SERVICE

INTENDED USE/INDICATIONS FOR USE SUMMARY

The InstruSafe® Instrument Protection Systems cassettes/trays are intended to contain and protect reusable medical devices during transport, sterilization, and storage. InstruSafe® Instrument Protection System cassettes/trays are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes/trays are intended to allow sterilization of the enclosed medical devices during these sterilization cycles:

- Pre-Vacuum Steam (EN 285)
- Ethylene Oxide (ISO 11135)
- Validated Gas Plasma Sterilization i.e.
  - STERRAD® 100S Standard
  - STERRAD® 100NX® Express
  - STERRAD® NX® Standard
  - STERRAD® 100NX® Standard
  - STERRAD® 100NX® Flex
  - STERIS® AMSCO® V-PRO 1®, V-PRO 1 Plus, V-PRO maX and V-PRO maX 2

The InstruSafe Instrument Protection System cassettes/trays are intended to be used in conjunction with a legally marketed wrap, Aesculap® rigid containers, or Genesis™ rigid containers. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

DEVICE DESCRIPTION

Summit Medical InstruSafe Instrument Protection Systems are cassettes/trays used to enclose and hold surgical instruments and instrument accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes/trays do not have direct patient contact. The cassettes/trays by themselves do not maintain sterility. The cassettes/trays are different sizes of the same basic configuration: a rectangular base with latchable cover. The cassettes/trays have perforations to allow sterilant penetration. The cassettes/trays contain silicone inserts in the base and/or cover to hold, organize, and protect the surgical instruments within the cassette/tray during the sterilization process and subsequent storage and transportation.

INTENDED USER

The InstruSafe® Instrument Protection Systems are intended to be used by healthcare professionals in the operating room and sterile processing department for transportation, sterilization, and storage of medical devices.

LIMITATION ON PROCESSING

1. The end of useful life on the InstruSafe Instrument Protection System is a minimum of 25 sterilization cycles. Inspect the tray before use for wear and damage caused by use. Discontinue use if visible signs of wear are present, including corrosion, mechanical failures, cracking, peeling, flaking, broken welds, damaged feet, damaged latches, damaged Hold-Its®/Hold-Downs®, discoloration, etc.
2. See **Table 2** for sterilization methods and configurations.
3. **DO NOT OVERLOAD** InstruSafe Systems or components.
4. **DO NOT OVERLOAD** individual Hold-Its® slots. Load only one instrument per Hold-Its® slot.
5. For rigid container users, **DO NOT WRAP** InstruSafe Systems or components and place inside of container for sterilization.
6. Inside of sterilizers, **DO NOT STACK** individually wrapped or containerized InstruSafe Systems or components. Separate wrapped or containerized InstruSafe Systems or components from each other or any other items on separate shelves of the sterilizer to allow for maximum sterilant flow.
7. The use of non absorbent tray liners (e.g. silicone fingered organizing mat) can cause condensate to pool. If visible moisture is present, re-sterilize with a longer dry time.
8. The total weight of the container system (e.g. container, tray, and instrument load) must not exceed 25 pounds (11.34 kg).
9. Instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions.
10. It is the responsibility of the processor to maintain specific validations for the terminal sterilization process being applied to the configurations of instruments and containers being presented to the sterilization process.

WARNINGS

- For aluminum InstruSafe Systems, use only neutral pH (6.0 – 8.5) detergents to avoid damaging the finish. A detergent with a highly acidic or highly alkaline pH could permanently damage the anodized aluminum finish of the cassette and metal components.
- Do not use if package is damaged or unintentionally opened prior to use.

Note: Clean and inspect cassettes according to the instructions provided prior to placing into service.

UNIVERSAL PRECAUTIONS

- Personnel should wear all personal protective clothing and equipment as required by their employer's/department's operating procedures for the contamination level they will be exposed to.
- Keep dissimilar metals separated during sterilization to prevent corrosion.

POINT OF USE

Remove gross soil with disposable cloth/paper wipe. Contaminated components should be kept moist until qualified cleaning processes can be applied.

CLEANING

Refer to the instrument manufacturer's instructions for use for specific instructions for cleaning the instruments in the cassettes.

Use one of the following validated cleaning options to clean the cassette/tray is recommended.

Use only neutral pH (6.0 – 8.5) solutions, mildly alkaline and free of sodium carbonate to avoid damaging finish for aluminum cassettes. **DO NOT** use scouring pads or abrasive cleaners. **DO NOT** store cassette in liquid.

1. Manual Gross Decontamination:

A. Materials needed: Neutral pH (6.0 – 8.5) enzymatic detergent, soft bristle brush, and running water.

B. Remove all visible soil and contaminates using a soft bristle brush. The entire cassette should be immersed while cleaning, to aid in the removal of contaminates and to reduce splashing of detergent on personnel, for a minimum of 2 minutes.

C. Rinse thoroughly for a minimum of 1 minute with clean water to remove all detergent. See rinsing instructions on the detergent label.

2. Ultrasonic Clean:

A. Prepare enzyme wash in an ultrasonic cleaning unit.

B. Place a single cassette in the detergent and run for a minimum of ten minutes.

C. Rinse for a minimum of 2 minutes with cold tap water.

D. Visually inspect cassette for contaminates. Repeat the cycle if necessary to remove visible contamination.

3. Automated Washer:

The InstruSafe Instrument Protection Systems have been validated for the automatic wash system cycle listed in **Table 1**. Qualification of specific parameters will need to be conducted by the processor.

Table 1

CYCLE	WATER TEMPERATURE	CLEANING PROCESS
Pre-Wash 1 & 2	Cold Tap Water	Re-Circulation Time: 2 Minutes
Enzyme Wash	Hot Tap Water	Soaking Time: 4 Minutes
Wash 1	Heated at 150°F (65.5°C)	Re-Circulation Time: 15 Minutes
Rinse 1 & 2	Hot Tap Water	Re-Circulation Time: 5 Minutes

Note: *After completion of an automatic wash cycle, visually inspect the InstruSafe System (cassette and accessories) for any remaining visible soil. All visible soil must be removed by hand cleaning, brushing, ultrasonic, or additional automatic cycles prior to sending to sterilization.*

DISINFECTION

InstruSafe systems are intended to be terminally sterilized.

MAINTENANCE, INSPECTION, AND TESTING

InstruSafe systems may be reused until unacceptable deterioration such as corrosion, cracking, rust, peeling, flaking, discoloration, or mechanical failure occurs.

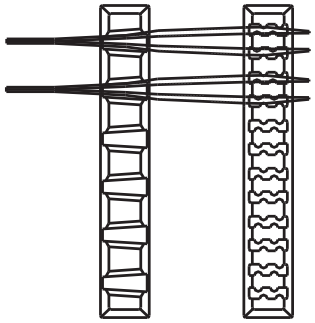
Signs of Mechanical Failure Include:

- Broken or cracked corners or welds
- Broken or non-working latches
- Missing, torn, or cut silicone inserts
- Missing or damaged feet

ASSEMBLY

1. Place the instruments in the predetermined holders or area defined by the locating posts so that all instrument surfaces will be exposed to sterilant. See **Figure A**. Be sure that only one instrument is in each slot. When possible, disassemble or open all parts of the instrumentation per the instrument manufacturer's instructions.
   DO NOT overload holders or exceed weight limits of cassettes. See Appendix A.

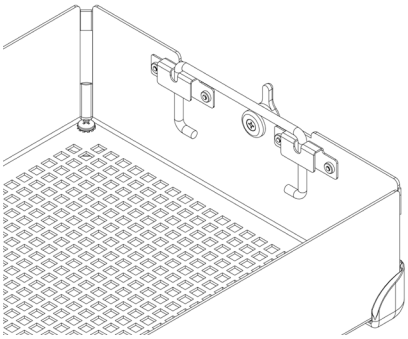
Figure A.



Note: *Instruments (e.g. endoscopes and instruments with lumens or channels) should be prepared and sterilized according to the instrument manufacturer's instructions for use.*

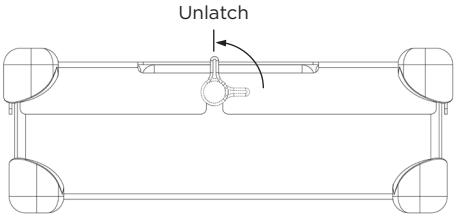
2. Ensure that handles are positioned inside the cassette (retracted position). Shown in **Figure B**.

Figure B.



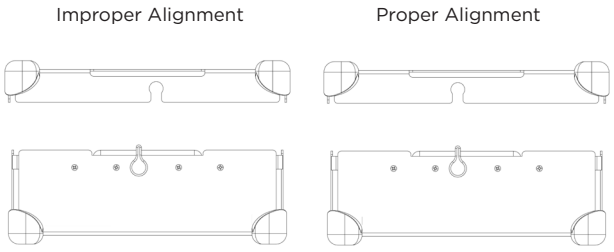
3. Place the cassette cover on the cassette base ensuring that the latches are properly positioned with the latch slot on the cassette cover, then close the latches. See **Figure C**.

Figure C.



Note: *The latches are offset so that the cassette cover always aligns properly with the base. This ensures that the holders are aligned when the cover is secured. See* ***Figure D*** *for proper alignment.*
DO NOT force the cassette cover onto the cassette base as it may damage instruments and the cassette.

Figure D.



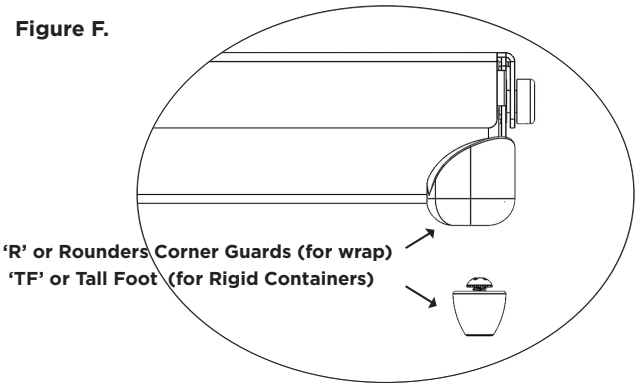
PACKAGING

InstruSafe Systems may be wrapped with a legally marketed wrap or placed in a legally marketed rigid container. Refer to the Indications for Use statements found in the instructions for use.

Using with Wrap:

1. Before wrapping the cassette, ensure it has the proper foot style. R should be used with wrap. See **Figure F**.

Figure F.



2. Wrap the cassette using legally marketed wrap per the wrap manufacturer's instructions.

3. Sterilize the pack using one of the sterilization cycles listed in the instructions for use.

Using with Rigid Container:

Refer to the Indications for Use statements found in the instructions for use.

1. Before placing the cassette in a rigid container ensure it has the proper foot style. TF should be used with a rigid container. See **Figure F**.

2. Place the cassette into the rigid container. Follow the container manufacturer's instructions for sealing the container.
   Note: *Do not wrap the cassettes before placing into the container for sterilization.*

3. Sterilize the container and contents using one of the sterilization cycles listed in the instructions for use.

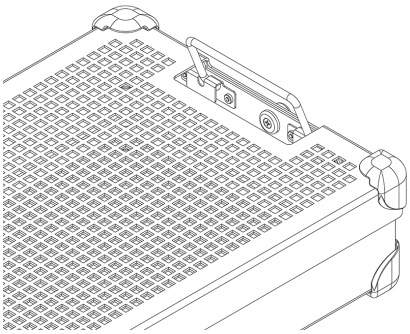
Additional Information:

To remove the cassette from a rigid container aseptically, follow container manufacturer's instructions for use.

1. With gloved hands, place palms outward and reach through the openings in the cassette cover.

2. Grasp the cassette handles and lift to their raised position. See **Figure G**.

Figure G.



3. Tilt the handles inward, away from the sides of the rigid container, and lift the cassette out of the container being careful to not touch the top or outside of the container.

4. Place cassette on a sterile surface.

STERILIZATION

See **Table 2** for typical sterilization parameters that have been qualified for the sterilization of InstruSafe Systems.

Table 2.

STERILIZATION METHOD	CYCLE *(times)*
Pre-Vacuum Steam	**Parameter:** Temperature 270°F (132°C) Expose Time 4 minutes Dry Time 30 minutes
Ethylene Oxide (EO)	**Preconditioning:** Temperature 131°F (55°C) Relative humidity 70 ± 15% Precondition time 1 hour **Sterilization:** Exposure time 120 minutes Temperature 131°F (55°C) Aeration time 12 hours
STERRAD 100S	*Standard*
STERRAD 100NX	*Standard*
STERRAD 100NX	*Express*
STERRAD 100NX	*Flex*
STERRAD NX	*Standard*
STERIS AMSCO V-PRO 1	*Standard*
STERIS AMSCO V-PRO 1 PLUS	*Lumen, Non-Lumen*
STERIS AMSCO V-PRO maX	*Lumen, Non-Lumen*
STERIS AMSCO V-PRO maX 2	*Lumen, Non-Lumen*

Summit Medical has validated the following sterilization methods:

- The 4 minute autoclave sterilization cycle in legally marketed wrap, Aesculap rigid container or Genesis rigid container cleared by the FDA.
- The Ethylene Oxide (EO) sterilization cycle in legally marketed wrap and a Genesis sterile container cleared by the FDA.
- The STERRAD 100S Standard sterilization cycle in legally marketed wrap and an Aesculap rigid container cleared by the FDA.
- The STERRAD 100NX Standard sterilization cycle in legally marketed wrap and an Aesculap rigid container cleared by the FDA.
- The STERRAD 100NX Express sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERRAD 100NX Flex sterilization cycle in legally marketed wrap and an Aesculap rigid container cleared by the FDA.
- The STERRAD NX Standard sterilization cycle in legally marketed wrap and an Aesculap rigid container cleared by the FDA.
- The STERIS AMSCO V-PRO, V-PRO 1 PLUS, V-PRO maX and V-PRO maX 2 sterilization cycles in legally marketed wrap and an Aesculap rigid container cleared by the FDA.

DO NOT exceed the load capacity of the sterile container as specified by the manufacturer.

Use an FDA cleared accessory to maintain sterility.

Please consult the sterilizer instruction manual to ensure intended loads are compatible with the intended sterilization cycle.

Please consult the container instructions for use to ensure that the intended load is compatible with the FDA cleared loads for the container.

INDICATIONS FOR USE

4 Minute Steam, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility.

Autoclave Sterilization Parameter	
Cycle	Pre-Vacuum
Temperature	270°F (132°C)
Exposure Time	4 minutes
Minimum Dry Time	30 minutes
Summit Cassette Model	**Aesculap Container Model**
IN-8823-AE	*JN444
IN-2880	*JK444
IN-6105	*JN742
**Validated by Summit Medical for use in Pre-Vacuum Steam sterilizers ONLY operating at 270°F (132°C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization container's intended load claims.*	

Lumen Claims for 4 Minute Pre-Vacuum Steam Sterilization Cylcle			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-8823-CF	3mm	400mm	4
IN-8823-CF	3mm	200mm	2
IN-2880	1mm	76mm	2
IN-2880	3mm	177mm	1
IN-6105	5mm	241mm	1
IN-2681	1mm	65mm	1
IN-2681	3mm	200mm	1
IN-7823	1mm	400mm	17

4 Minute Steam, Genesis™ Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed Genesis rigid containers. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

Lumen Claims for 4 Minute Pre-Vacuum Steam Sterilization Cylcle			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-2681	1mm	65mm	1
IN-2681	3mm	200mm	1
IN-6105	5mm	241mm	1
IN-0000	1mm	400mm	5
	3mm	400mm	1
	5mm	400mm	1

INDICATIONS FOR USE (continued)

8 Minute Steam & Ethylene Oxide (EO), Wrap & Genesis™ Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe System cassettes are intended to allow sterilization of the enclosed medical devices during Pre-Vacuum steam or ethylene oxide sterilization cycles. The InstruSafe System cassettes are intended to be used in conjunction with central legally marketed wrap or with a Genesis rigid container. The InstruSafe System cassettes are not intended on the own to maintain sterility.

Sterilization methods and configurations

Steam 8 Minute Preconditioning at 132°C	
140 count woven wrap	10 minute dry time
Non-woven wrap (Kimberly Clark)	50 minute dry time
Genesis Container (reference Table 1 for filter paper to use)	30 minute dry time

Ethylene Oxide (EO)
▪ 1 hour preconditioning at 131°F (55°C) with relative Humidity of 70 ± 15% ▪ 2 hours exposure at 131°F (55°C) ▪ 12 hours aeration

Table 1

Genesis Container	Genesis Container Filter Paper
CD2-4B	FX3-1: 9x9″
CD2-5B	FX3-1: 9x9″
CD3-4B	FX3-1: 9x9″
CD3-5B	FX3-1: 9x9″
CD3-6B	FX3-1: 9x9″
CD3-7B	FX3-1: 9x9″
CD4-5B	FO3-2: 9x6″
CD5-61B	FO3-2: 9x6″
CD6-6B	FX3-1: 9x9″

See V. Mueller Genesis Sterilizer Container system User's Operating Instructions when using any Genesis Rigid Container.

STERRAD® 100S & STERRAD® 100NX® Standard Cycles, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad 100S Standard and Sterrad 100NX Standard sterilization cycles. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

The following sterilization trays were validated with the corresponding rigid containers:

STERRAD 100S Standard Cycle	
Summit Cassette Model	**Aesculap Container Model**
IN-8823-AE	*JM444
IN-6105	*JM440

STERRAD 100NX Standard Cycle	
Summit Cassette Model	**Aesculap Container Model**
IN-8823-AE	*JM444
IN-6105	*JM440

**Validated by Summit Medical for use in STERRAD 100S Standard Cycle and STERRAD 100NX Standard Cycle ONLY. Consult container instructions to ensure that contents do not exceed the sterilization container's intended load claims.*

Lumen Claims for STERRAD 100S Standard and STERRAD 100NX Standard Cycles	
4 Stainless steel lumens with 3mm inner diameter x 400mm length	All appropriately sized models are listed in Appendix A with the exception of IN-2681.
2 Stainless steel lumens with 3mm inner diameter x 200mm length	
1 Stainless steel lumens with 3mm inner diameter x 200mm length	IN-2681
1 Stainless steel lumens with 1mm inner diameter x 65mm length	

INDICATIONS FOR USE (continued)

STERRAD® NX® Standard Cycle, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad NX Standard Sterilization Cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

Sterilization Methods and configurations
- Sterrad NX Standard Sterilization Cycle

Lumen Claims for STERRAD NX Standard Sterilization Cycle			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-2681	1mm	65mm	1
IN-2681	3mm	200mm	1
IN-8987-S	1mm	500mm	5
IN-8615	2.3mm	210mm	5
IN-6105	4mm	235mm	1
Note: *The worst case validated load based on vent-to-volume calculation is the IN-2681 tray.*			

STERRAD® 100NX® Express Cycle, Wrap

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad® 100NX Express Cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. The InstruSafe Instrument Protection System has no lumen claims for the Sterrad 100NX Express Cycle.

STERRAD® 100NX® Flex Sterilization Cycle, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad 100NX Flex Sterilization Cycle. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

STERRAD 100NX Flex Sterilization Cycle	
Summit Cassette Model	**Aesculap Container Model**
IN-0000	*JM440
IN-6105	*JM440
**Validated by Summit Medical for use in STERRAD 100NX Flex Sterilization Cycle ONLY. Consult container instructions to ensure that contents do not exceed the sterilization container's intended load claims.*	

Lumen Claims for STERRAD 100NX Flex Sterilization Cycle				
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**	**Wrap/Rigid Container**
IN-0000	1mm	850mm	1	Wrap + Rigid Container
IN-8823	1mm	850mm	1	Wrap + Rigid Container
IN-7344	1mm	850mm	1	Wrap
IN-6105	4mm	235mm	1	Wrap + Rigid Container

The worst case validated load based on vent-to-volume calculation is the IN-0000 tray.

Note: *The IN-0000 tray is for testing purposes only.*

INDICATIONS FOR USE (continued)

AMSCO® V-PRO® Low Temperature Sterilization Cycles, Wrap & Aesculap® Rigid Container

InstruSafe® Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during Amsco V-PRO Low Temperature Sterilization Cycles. The InstruSafe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The InstruSafe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

AMSCO V-PRO Low Temperature Sterilization Systems			
Sterilizer	**Standard Cycle**	**Lumen Cycle**	**Non Lumen Cycle**
V-PRO 1	X	N/A	N/A
V-PRO 1 PLUS	N/A	X	X
V-PRO maX	N/A	X	X
V-PRO maX 2	N/A	X	X
Summit Cassette Model		**Aesculap Container Model**	
IN-8823		*JM444	
IN-6105		*JM742	

**Validated by Summit Medical for use in AMSCO V-PRO Low Temperature Sterilization Systems ONLY. When using Aesculap container as sterile barrier, the load (Summit tray and contents), should not exceed the load claims for the container is weight or load type.*

Lumen size of instrumentation validated includes:			
Summit Cassette Model	**Minimum Inside Diameter**	**Maximum Length**	**Number of Lumens**
IN-8823	3mm	400mm	2
IN-6105	3mm	200mm	1
IN-2681	1mm	64mm	1

Note: *The worst case validated load based on vent-to-volume calculation is the IN-2681 tray.*

STORAGE

Store terminally sterile cassettes that are wrapped or containerized on storage shelf in a horizontal position. Consult wrap or container manufacturer for shelf life information.

DISPOSAL

In the event the InstruSafe® Instrument Protection Systems do not pass inspection prior to use or have otherwise been deemed no longer fit for purpose, the devices shall be disposed of in line with local protocol. The method of disposal shall depend on the potential risks of cross-contamination and infection when the need for disposal is identified.

SERIOUS INCIDENT REPORTING

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

WARRANTY

LIMITED WARRANTY FOR SUMMIT MEDICAL INSTRUSAFE INSTRUMENT PROTECTION SYSTEM.

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This Limited Warranty gives you specific legal rights, and you may also have other rights which vary from State to State. Some States do not allow limitations on how long an implied warranty lasts, or do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusions may not apply to you.

What Is Covered. Summit Medical warrants the original purchaser that the InstruSafe system enclosed with this Limited Warranty conforms to the manufacturer's specifications and is free from defects in workmanship and material for a period of 12 months from the date of original purchase. If the original purchaser transfers the InstruSafe System to another party, this Limited Warranty will not be enforceable by the party to whom the product is transferred.

What We Will Do To Correct Problems. Should your InstruSafe System prove defective during this period, you must notify Summit Medical or an authorized distributor or dealer of Summit Medical. You must permit Summit Medical or its representatives to make such investigation, examination and tests as Summit Medical deems appropriate and, if requested to do so, you will return the product to the factory at the address set forth below. Summit Medical's sole obligation under this Limited Warranty is, at its option, to repair or replace the defective product or products, without charge for parts or labor. Postage, insurance or shipping costs incurred in presenting your InstruSafe System product for warranty service are your responsibility.

What Is Not Covered. This Limited Warranty is contingent upon proper use and maintenance of the product; it does not cover products that have been improperly shipped, or that have been misused, abused, neglected, or improperly maintained, cleaned or stored, or that have been serviced other than by Summit Medical or an authorized distributor or dealer of Summit Medical or that have been modified without the express approval of Summit Medical. Failure to follow the directions in the owner's manual may constitute improper use or maintenance of the product and causes this Limited Warranty not to apply. This Warranty does not extend to normal wear or to replacement items.

If you have questions or claims related to this warranty, contact:
Customer Service Department
Summit Medical
815 Vikings Parkway, Suite 100
St. Paul, MN 55121 | USA
www.instrusafe.com

PHONE: 651-789-3939 | 888-229-2875
FAX: 651-789-3979 | 888-229-1941
EMAIL: customerservice@innoviamedical.com

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Symbol Reference Key / Légende des symboles / Symbollegende / Legenda dei simboli / Clave de referencia de los símbolos / Chave de referência de símbolo / Legenda / Symbol Referensnyckel / Symbolreferencenøgle / Symbolien merkitys / Υπόμνημα συμβόλων / Objaśnienie symboli / Simge Referans Anahtarı / Расшифровка символов / Použité symboly / Szimbólumok magyarázata / Referenčný kľúč k symbolom / Symbolreferansenøkkel / Referenčni ključ simbola / Легенда на символите / Tastă simbol de referință / Sümbolite legend / Simbolu skaidrojums / Referentni ključ simbola / Legenda simbola / Simbolių paaiškinimas / 符号参考图例 / 符號參考圖例 / 기호 참조 키 / 記号参照キー

	Consult instructions for use / Consulter les recommandations d'utilisation / Gebrauchsanweisung beachten / Consultare le istruzioni per l'uso / Consulte las instrucciones de uso / Consulte as instruções de uso / Raadpleeg de gebruiksaanwijzing / Se bruksanvisningen / Se brugsanvisning / Lue käyttöohjeet / Συμβουλευθείτε τις οδηγίες χρήσης / Należy zapoznać się z instrukcją obsługi / Kullanım talimatlarına bakın / См. инструкции по эксплуатации / Přečtěte si návod k použití / Tekintse át a használati útmutatót / Pozrite návod na použitie / Se bruksanvisning / Preglejte navodila za uporabo / Направете справка в инструкциите за употреба / Consultați instrucțiunile de utilizare / Vaadake kasutusjuhendit / Skatīt lietošanas instrukciju / Pročitati upute za uporabu / Pogledajte uputstvo za upotrebu / Žr. naudojimo instrukciją / 请参阅使用说明书 / 請參閱使用說明書 / 사용 지침 참조 / 使用説明書を参照してください
	Quantity / Quantité / Stückzahl / Quantità / Cantidad / Quantidade / Aantal / Antal / Antal / Määrä / Ποσότητα / Ilość / Miktar / Количество / Množství / Mennyiség / Množstvo / Mengde / Količina / Количество / Cantitate / Kogus / Daudzums / Količina / Količina / Kiekis / 量 / 數量 / 수량 / 数量
NON STERILE	Non-sterile / Non stérile / Unsteril / Non sterile / No estéril / Não esterilizado / Niet-steriel / Icke-steril / IKKE-STERIL / Ei steriili / Μη αποστειρωμένο / Niesterylny / Steril değildir / Нестерильно / Nesterilní / Nem steril / Nesterilné / Ikke steril / Nesterilno / Нестерилно / Nesterile / Mittesteriilne / Nesterils / Nesterilno / Nesterilno / Nesterilu / 非灭菌 / 非滅菌 / 비-멸균 / 非滅菌
REF	Catalogue number / Numéro de catalogue / Artikelnummer / Numero di catalogo / Número de catálogo / Número de catálogo / Catalogusnummer / Katalognummer / Katalognummer / Luettelonumero / Αριθμός καταλόγου / Numer katalogowy / Katalog Numarası / Номер по каталогу / Katalogové číslo / Katalógus szám / Katalógové číslo / Katalognummer / Kataloška številka / Каталожен номер / Numărul de catalog / Kataloogi number / Kataloga numurs / Kataloški broj / Kataloški broj / Katalogo numeris / 目录号 / 目錄號 / 카탈로그 번호 / カタログ番号
LOT	Batch Code / Code de lot / Chargennummer / Codice lotto / Código de lote / Código do lote / Batchcode / Satsnummer / Partikode / Eränumero / Κωδικός παρτίδας / Kod partii / Parti Kodu / Код партии / Kód šarže / Tételkód / Kód šarže / Partikode / Koda serije / Код на партида / Cod lot / Partii kood / Sērijas numurs / Šifra serije / Kód serije / Partijos kodas / 批号 / 批號 / 배치 코드 / バッチコード
	Date of Manufacture / Date de fabrication / Herstellungsdatum / Data di produzione / Fecha de fabricación / Data de fabricação / Productiedatum / Tillverkningsdatum / Fremstillingsdato / Valmistuspäivä / Ημερομηνία κατασκευής / Data produkcji / Üretim Tarihi / Дата производства / Datum výroby / Gyártás dátuma / Dátum výroby / Produksjonsdato / Datum proizvodnje / Дата на производство / Data producției / Tootmise kuupäev / Izgatavošanas datums / Datum proizvodnje / Datum proizvodnje / Pagaminimo data / 生产日期 / 生產日期 / 제조일 / 製造日
	Caution / Attention / Vorsicht / Attenzione / Precaución / Cuidado / Opgelet / Försiktighetsåtgärd / Forsigtig / Varoitus / Προσοχή / Przestroga / Dikkat / Внимание / Výstraha / Figyelem! / Upozornenie / Advarsel / Pozor / Внимание / Atenție / Ettevaatust / Uzmanību! / Oprez / Oprez / Démesio / 注意 / 注意 / 주의 / 注意
	Manufacturer / Fabricant / Hersteller / Produttore / Fabricante / Fabricante / Fabrikant / Tillverkare / Producent / Valmistaja / Κατασκευαστής / Producent / Üretici / Производитель / Výrobce / Gyártó / Výrobca / Produsent / Proizvajalec / Производител / Producător / Tootja / Ražotājs / Proizvođač / Proizvođač / Gamintojas / 制造商 / 製造商 / 제조사 / 製造元
US	Country of Manufacture (Made in the US) / Pays de fabrication (Fabriqué aux États-Unis) / Herstellungsland (Hergestellt in den USA) / Paese di produzione (fabbricato negli Stati Uniti) / País de fabricación (Hecho en EE. UU.) / País de fabricação (Feito nos Estados Unidos) / Land van vervaardiging (gemaakt in de Verenigde Staten) / Tillverkningsland (Tillverkad i USA) / Fremstillingsland (fremstillet i USA) / Valmistusmaa (valmistettu Yhdysvalloissa) / Χώρα κατασκευής (Κατασκευασμένο στις ΗΠΑ) / Kraj produkcji (Wyprodukowano w USA) / Üretildiği Ülke (ABD Malıdır) / Страна производителя (сделано в США) / Země výroby (vyrobeno v USA) / A gyártó országa (Made in the US) / Krajina výroby (vyrobené v USA) / Produksjonsland (produsert i USA) / Država proizvajalca (izdelano v ZDA) / Страна производител (Произведено в САЩ) / Țara de fabricație (Fabricat în SUA) / Valmistajariik (valmistatud USAs) / Ražotājvalsts (Ražots ASV) / Žemlja proizvođača (proizvedeno u SAD-u) / Zemlja proizvodnje (proizvedeno u SAD) / Pagaminimo šalis (pagaminta JAV) / 生产国（美国制造） / 生產國（美國製造） / 제조국(미국산) / 製造国（米国製）
	Do not use if package is damaged / Ne pas utiliser si l'emballage est endommagé / Nicht verwenden, wenn die Verpackung beschädigt ist / Non utilizzare in caso di imballaggio danneggiato / No utilizar si el paquete está dañado / Não use se a embalagem estiver danificada / Niet gebruiken als de verpakking beschadigd is / Får inte användas om förpackningen är skadad / Må ikke bruges, hvis emballagen er beskadiget / Älä käytä, jos pakkaus on vahingoittunut / Μην χρησιμοποιείτε αν η συσκευασία είναι κατεστραμμένη / Nie używać, jeśli opakowanie jest uszkodzone / Ambalaj hasarlıysa kullanmayın / Не использовать, если упаковка повреждена / Nepoužívejte, pokud je obal poškozen / Ne használja, ha a csomagolás sérült / Nepoužívajte, ak je obal poškodený / Ikke bruk hvis pakningen er skadet / Ne uporabljajte, če je ovoj poškodovan / Да не се използва, ако опаковката е повредена / A nu se utiliza dacă ambalajul este deteriorat / Mitte kasutada, kui pakend on viga saanud / Nelietot, ja iepakojums ir bojāts / Nemojte upotrebljavati ako je ambalaža oštećena / Ne koristite ako je pakovanje oštećeno / Nenaudokite, jei pakuotė pažeista / 如果包装破损，请勿使用 / 如果包裝損壞，請勿使用 / 포장이 손상된 경우 사용하지 마십시오. / 梱包が破損している場合は使用しないこと
MD	Medical Device / Dispositif médical / Medizinprodukt / Dispositivo medico / Dispositivo médico / Dispositivo Médico / Medisch hulpmiddel / Medicinsk apparat / Medicinsk udstyr / Lääketieteellinen laite / Ιατρική συσκευή / Wyrób medyczny / Tıbbi Cihaz / Медицинское изделие / Lékařské zařízení / Orvostechnikai eszköz / Zdravotnícke pomôcky / Medisinsk utstyr / Medicinski pripomoček / Медицинско изделие / Dispozitiv medical / Meditsiiniseade / Medicīniska ierīce / Medicinski uređaj / Medicinski uređaj / Medicinos prietaisas / 医疗器械 / 醫療器械 / 의료 기기 / 医療機器
EC REP	Authorized Representative in the European Community/European Union / Représentant autorisé établi au sein de la Communauté européenne/l'Union européenne / Bevollmächtigte Vertretung in der Europäischen Gemeinschaft/Europäischen Union / Rappresentante autorizzato nella Comunità europea/Unione europea / Representante autorizado en la Comunidad Europea/Unión Europea / Representante Autorizado na Comunidade Europeia/União Europeia / Officiële vertegenwoordiger in de Europese Gemeenschap / Europese Unie / Auktoriserad representant inom Europeiska gemenskapen/Europeiska unionen / Autoriseret repræsentant i Det Europæiske Fællesskab/Den Europæiske Union / Valtuutettu edustaja Euroopan yhteisössä/Euroopan unionissa / Εγκεκριμένος αντιπρόσωπος στην Ευρωπαϊκή Κοινότητα/Ευρωπαϊκή Ένωση / Upoważniony przedstawiciel we Wspólnocie Europejskiej / Unii Europejskiej / Avrupa Topluluğu'nda/Avrupa Birliği'nde Yetkili Temsilci / Уполномоченный представитель в Европейском сообществе / Европейском союзе / Autorizovaný zástupce v Evropském společenství/Evropské unii / Meghatalmazott képviselő az Európai Közösségben/Európai Unióban / Oprávnený zástupca v Európskom spoločenstve/Európskej únii / Autorisert representant i Det europeiske felleskapet / EU / Pooblaščeni predstavnik v Evropski skupnosti/Evropski uniji / Упълномощен представител в Европейската общност/Европейския съюз / Reprezentant autorizat în Comunitatea Europeană/Uniunea Europeană / Volitatud esindaja Euroopa Ühenduses / Euroopa Liidus / Pilnvarotais pārstāvis Eiropas Kopienā/Eiropas Savienībā / Ovlašteni predstavnik u Europskoj zajednici / Europskoj uniji / Ovlašćeni predstavnik u Evropskoj zajednici/Evropskoj uniji / Igaliotasis atstovas Europos Bendrijoje / Europos Sąjungoje / 欧洲共同体/欧洲联盟的授权代表 / 歐洲共同體/歐洲聯盟的授權代表 / 유럽 공동체/유럽 연합의 공인 대리인 / 欧州共同体/欧州連合の認定代理業者
UDI	Unique Device Identifier / Identifiant unique du dispositif (UDI) / Eindeutige Gerätekennung / ID univoco del dispositivo / Identificador único del dispositivo / Identificador Único de Dispositivo / Unieke apparaat-id / Unik enhetsidentifierare / Unikt enheds-ID / Yksilöllinen laitetunniste / Μοναδικό αναγνωριστικό συσκευής / Niepowtarzalny identyfikator wyrobu / Benzersiz Cihaz Kimliği / Уникальный идентификационный номер изделия / Jedinečný identifikátor zařízení / Egyedi eszközazonosító / Jedinečný identifikátor zariadenia / UDI (Unique Device Identifier) / Enolični identifikator naprave / Уникален идентификатор на изделието / Identificator unic al dispozitivului / Kordumatu identifitseerimistunnus / Ierīces unikālais identifikators / Ovlašteni predstavnik u Europskoj zajednici / Europskoj uniji / Jedinstveni identifikator uređaja / Unikalus prietaiso identifikatorius / 唯一设备标识符 / 唯一設備標識符 / 기기 고유 식별자 / 機器固有識別子
	Not made with natural rubber latex. / Ne contient pas de latex de caoutchouc naturel. / Ohne Naturkautschuklatex hergestellt. / Non fabbricato con lattice di gomma naturale. / No hecho con látex de caucho natural. / Não fabricado com látex de borracha natural. / Niet gemaakt met natuurlijk rubber latex. / Ej tillverkad med latex naturgummi. / Ikke fremstillet med naturgummilatex. / Ei sisällä luonnonkumilateksia. / Δεν κατασκευάζεται με τη χρήση φυσικού λάτεξ. / Nie jest wykonana z naturalnego lateksu gumowego. / Doğal kauçuk lateksten yapılmamıştır. / При производстве не использовался латекс натурального каучука. / Při výrobě nebyl použit přírodní kaučukový latex. / Nem természetes gumiból készült. / Nie je vyrobené z prírodného latexu. / Ikke laget av naturlig gummilateks. / Ni izdelano iz naravne gume iz lateksa. / Не съдържа естествен латекс. / Nu este fabricat din latex de cauciuc natural. / Pole valmistatud loodusliku kummilateksiga. / Nesatur dabīgā kaučuka lateksu. / Nije proizveden od prirodnog gumenog lateksa. / Ne sadrži prirodni gumeni lateks. / Pagaminta nenaudojant gamtinio kaučiuko latekso. / 并非由天然胶乳制成。 / 並非由天然膠乳製成。 / 천연 고무 라텍스로 제작되지 않음. / 天然ゴムラテックス製ではありません。

CE

EC REP

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