Sonata® SYSTEM

SONATA IUUS PROBE REPROCESSING TRAY
OM-1000-GS

(EN) IUUS PROBE REPROCESSING TRAY **INSTRUCTIONS FOR USE: English**

(FR) PLATEAU DE RECONDITIONNEMENT DE SONDE IUUS **MODE D'EMPLOI: Français**

(DE) WIEDERAUFBEREITUNGSSCHALE FÜR IUUS-SONDEN **GEBRAUCHSANWEISUNG: Deutsch**

(IT) VASSOIO DI RICONDIZIONAMENTO PER LA IUUS PROBE **ISTRUZIONI PER L'USO: Italiano**

(ES) BANDEJA DE REPROCESAMIENTO DE SONDA IUUS **INSTRUCCIONES DE USO: Español**

(PT-BR) BANDEJA DE REPROCESSAMENTO DE SONDA IUUS **INSTRUÇÕES DE UTILIZAÇÃO: Português**

(NL) IUUS PROBE-HERVERWERKINGSSCHAAL **GEBRUIKSAANWIJZING: Nederlands**

(SV) IUUS TRÅG FÖR OMBEARBETNING AV PROB **ANVÄNDARINSTRUKTIONER: Svenska**

(DA) IUUS PROBE GENINDVINDINGSKASSETTE **BRUGSANVISNING: Dansk**

(FI) IUUS-ANTURIN UUDELLEENKÄSITTELYTELINEEN **KÄYTTÖOHJEET: Suomi**

(EL) ΔΙΣΚΟΣ ΕΠΑΝΕΠΕΞΕΡΓΑΣΊΑΣ ΑΝΙΧΝΕΥΤΉ IUUS **ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ: Ελληνικά**

(PL) TACA DO STERYLIZACJI IUUS PROBE **INSTRUKCJA UŻYTKOWANIA: Polski**

(TR) IUUS PROBE YENİDEN İŞLEM TEPSİSİ **KULLANMA TALİMATLARI: Türkçe**

(RU) IUUS ДЛЯ ПОВТОРНОЙ ОБРАБОТКИ ЗОНДА **ИНСТРУКЦИИ ПО ЭКСПЛУАТАЦИИ: Русский**

(CS) TÁC NA ZPRACOVÁNÍ SONDY IUUS **NÁVOD K POUŽITÍ: Čeština**

(HU) IUUS PROBE REGENERÁLÓ TÁLCA **HASZNÁLATI ÚTMUTATÓ: Magyar**

(SK) PODNOS NA OPÄTOVNÉ SPRACOVANIE SOND IUUS **POKYNY NA POUŽITIE: Slovenčina**

(NO) REPROSESSERINGSBRETTET FOR IUUS-SONDE **BRUKSANVISNING: Norsk**

(SL) PLADENJ ZA PONOVNO OBDELAVO IUUS PROBE **NAVODILA ZA UPORABO: Slovensko**

(BG) ТАБЛА ЗА ПРЕРАБОТКА IUUS PROBE **ИНСТРУКЦИИ ЗА УПОТРЕБА: български**

(RO) TAVA DE REPROCESARE IUUS PROBE **INSTRUCȚIUNI DE UTILIZARE: Română**

(ET) IUUS PROBE TAASTÖÖTLUSALUS **KASUTUSJUHEND: Eesti**

(LV) IUUS ZONDES ATKĀRTOTAS APSTRĀDES PAPLĀTE **LIETOŠANAS INSTRUKCIJA: Latviski**

(HR) PLITICA ZA PONOVNO PROCESIRANJE IUUS SONDI **UPUTE ZA UPORABU: Hrvatski**

(SR) TACNA ZA PONOVNU OBRADU SONDE IUUS PROBE **UPUTSTVA ZA UPOTREBU: Srpski**

(LT) "IUUS PROBE" PAKARTOTINIO APDOROJIMO PADĖKLAS **NAUDOJIMO INSTRUKCIJA: Lietuvių k.**

(ZH-CN) IUUS 探针再处理托盘 **使用说明书: 简体中文**

(ZH) IUUS 探針再處理託盤 **使用說明書: 繁體中文**

(KO) IUUS PROBE 재처리 트레이 **용도 표기: 한국어**

(JA) IUUSプローブ再処理トレイ **取扱説明書: 日本語**

For the full instructions for use visit:
Pour le mode d'emploi complet, visitez le site :
Die vollständige Gebrauchsanweisung finden Sie unter:
Per le istruzioni per l'uso complete visitare:
Para ver las instrucciones de uso completas, visite:
Para as instruções completas de utilização visite:
Ga voor de volledige gebruiksaanwijzing naar:
För att få tillgång till hela bruksanvisningen, besök:
Se hele brugsanvisningen her:
Täydelliset käyttöohjeet ovat osoitteessa:
Για πλήρεις οδηγίες χρήσης, επισκεφτείτε:
Pełną instrukcję użytkowania można znaleźć na stronie:
Kullanma talimatlarının tamamı için şu adresi ziyaret edin:
Для получения полных инструкций по эксплуатации посетите:
Pro úplný návod k použití navštivte:
A teljes használati utasításért látogasson el ide:
Úplné pokyny na použitie nájdete na:
For en komplett bruksanvisning, gå til:
Za celotna navodila obiščite:
За пълните инструкции за употреба посетете:
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Išsamią naudojimo instrukciją rasite:
有关完整的使用说明，请访问：
有關完整的使用說明，請瀏覽：
전체 사용 지침은 다음 사이트를 방문하십시오:
使用説明書の詳細については、以下をご覧ください。

https://summitmedicalusa.com/ifu/documents/26523-private-label-ifu/

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 IUUS Probe Reprocessing Tray OM-1000-GS (Instrument Protection System) is intended to contain and protect the Sonata® Intrauterine Ultrasound (IUUS) Probe model IUSP-002 during transport, sterilization, and storage. The IUUS Probe Reprocessing Tray is used to organize and protect IUUS Probes that are sterilized by a healthcare provider. The IUUS Probe Reprocessing Tray is intended to allow sterilization of the enclosed IUUS Probe model IUSP-002 during these sterilization cycles:

- STERRAD® 100NX® Standard
- STERIS® AMSCO® V-PRO 1®, V-PRO 1 Plus, V-PRO maX and V-PRO maX 2

The IUUS Probe Reprocessing Tray is intended to be used in conjunction with a legally marketed wrap. The IUUS Probe Reprocessing Tray is not intended on its own to maintain sterility. A full list of device models is provided in Appendix A.

DEVICE DESCRIPTION

IUUS Probe Reprocessing Trays manufactured by Summit Medical are used to enclose and hold the Sonata® IUUS Probe model IUSP-002 in an organized manner during the sterilization process and subsequent storage and transportation. The tray does not have direct patient contact. The tray by itself does not maintain sterility. The tray has a rectangular base with latchable cover. The tray has perforations to allow sterilant penetration. The tray contains silicone inserts in the base and/or cover to hold, organize, and protect the IUUS Probe within the tray during the sterilization process and subsequent storage and transportation.

INTENDED USER

The IUUS Probe Reprocessing Tray is intended to be used by healthcare professionals in the operating room and sterile processing department for transportation, sterilization, and storage of the Sonata® IUUS Probe model IUSP-002.

LIMITATION ON PROCESSING

1. The end of useful life on the IUUS Probe Reprocessing Tray 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** Systems or components.
4. **DO NOT OVERLOAD** individual Hold-Its® slots. Load only one instrument per Hold-Its® slot.
5. Inside of sterilizers, **DO NOT STACK** individually wrapped Systems or components. Separate wrapped Systems or components from each other or any other items on separate shelves of the sterilizer to allow for maximum sterilant flow.
6. The total weight of the system (e.g. tray, and instrument load) must not exceed 25 pounds (11.34 kg).
7. The Sonata® IUUS Probe should be prepared and sterilized according to the IUUS Probe manufacturer's instructions.
8. It is the responsibility of the processor to maintain specific validations for the terminal sterilization process being applied to the configurations of instruments being presented to the sterilization process.

WARNINGS

- Do not use if package is damaged or unintentionally opened prior to use.

Note: Clean and inspect trays 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 trays.

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

DO NOT use scouring pads or abrasive cleaners. **DO NOT** store tray in liquid.

NOTE: These cleaning methods and cycles are validated for the tray ONLY. Refer to the Sonata® IUUS Probe Instructions for Use (REF-003, IUSP-002 Manual) for validated cleaning methods for the IUSP-002 IUUS Probe in the tray OM-1000-GS.

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 tray 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 tray 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 tray for contaminates. Repeat the cycle if necessary to remove visible contamination.

3. Automated Washer:

The 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 System (tray 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

Systems are intended to be terminally sterilized.

MAINTENANCE, INSPECTION, AND TESTING

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

STERILIZATION

See **Table 2** for typical sterilization parameters that have been qualified for the sterilization of Sonata IUUS Probe Reprocessing Tray.

NOTE: These sterilization methods and cycles are validated for the tray ONLY. Refer to the Sonata® IUUS Probe Instructions for Use (REF-003, IUSP-002 Manual) for validated sterilization methods for the IUSP-002 IUUS Probe in the tray OM-1000-GS.

Table 2.

STERILIZATION METHOD FOR TRAY	CYCLE *(times)*
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 STERRAD 100S Standard sterilization cycle in legally marketed wrap cleared by the FDA.
- The STERRAD 100NX Standard sterilization cycle in legally marketed wrap 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 cleared by the FDA.
- The STERRAD NX Standard sterilization cycle in legally marketed wrap 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 cleared by the FDA.

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.

Ensure IUUS Probe Reprocessing Tray and enclosed instrument are completely dry before STERRAD or STERIS V-PRO sterilization.

INDICATIONS FOR USE STERILIZATION OF IUUS PROBE IS ONLY VALIDATED FOR WRAP, STERRAD 100NX AND V-PRO CYCLES

STERRAD® 100S & STERRAD® 100NX® Standard Cycles, Wrap

InstruSafe® Instrument Protection System trays are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System trays 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 trays are intended to be used in conjunction with legally marketed wrap. The InstruSafe Instrument Protection System trays are not intended on their own to maintain sterility. A full list of device models is provided in Appendix A.

**Validated by Summit Medical for use in STERRAD 100S Standard Cycle and STERRAD 100NX Standard Cycle ONLY.*

AMSCO® V-PRO® Low Temperature Sterilization Cycles, Wrap

InstruSafe® Instrument Protection System trays are used to organize and protect other medical devices that are sterilized by a healthcare provider. InstruSafe Instrument Protection System trays are intended to allow sterilization of the enclosed medical devices during Amsco V-PRO Low Temperature Sterilization Cycles. The InstruSafe Instrument Protection System trays are intended to be used in conjunction with a legally marketed wrap. The InstruSafe Instrument Protection System trays 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
**Validated by Summit Medical for use in AMSCO V-PRO Low Temperature Sterilization Systems ONLY.*			

STORAGE

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

DISPOSAL

In the event the 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 INSTRUMENT PROTECTION SYSTEM.

THIS LIMITED WARRANTY AND THE REMEDY PROVIDED HEREIN ARE EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES AND, UNLESS STATED HERE-IN, ANY STATEMENTS OR REPRESENTATIONS MADE BY ANY OTHER PERSON OR FIRM ARE VOID. THE DURATION OF ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE SHALL BE LIMITED TO THE DURATION OF THE EXPRESS LIMITED WARRANTY. NEITHER SUMMIT MEDICAL NOR ITS AFFILIATES SHALL BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL LOSSES OR DAMAGES, RESULTING FROM THE USE OR INABILITY TO USE THE SYSTEM, WHETHER RESULTING FROM BREACH OF WARRANTY OR ANY OTHER LEGAL THEORY.

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 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 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 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 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

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
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	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 / Nesterilnĺ / Nem steril / Nesterilné / Ikke steril / Nesterilno / Нестерилно / Nesterile / Mittesteriilne / Nesterils / Nesterilno / Nesterilno / Nesterilu / 非灭菌 / 非滅菌 / 비-멸균 / 非滅菌
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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 / Dėmesio / 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) / Zemlja 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
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#	Model Number / Numéro de modèle / Modellnummer / Codice modello / Número de modelo / Número do modelo / Modelnummer / Modellnummer / Modelnummer / Mallinumero / Αρ. μοντέλου / Numer modelu / Model numarası / Номер модели / Číslo modelu / Modellszám / Číslo modelu / Modellnummer / Številka modela / Номер на модел / Număr model / Mudeli number / Modeļa numurs / Broj modela / Broj modela / Modelio numeris / 型号 / 型號 / 모델 번호 / モデル番号

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。

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